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TITLE 856 INDIANA BOARD OF PHARMACY

Proposed Rule
LSA Document #05-102

DIGEST

Adds 856 IAC 3-1-2 and 856 IAC 3-1-3, amends 856 IAC 3-2-3, and adds 856 IAC 3-3 through 856 IAC 3-7 to implement rule changes based on House Enrolled Act 1098-2005 (P.L.212-2005), including establishing criteria for drug returns, establishing the definitions and requirements for normal distribution chain of custody, pedigree, and the extent to which pedigrees are required, and establishing criteria to approve an accreditation body to evaluate and inspect a person who engages in wholesale distributions of legend drugs. Repeals 856 IAC 3-2-1, 856 IAC 3-2-7, and 856 IAC 3-2-8. Effective January 1, 2006.

856 IAC 3-1-2
856 IAC 3-1-3
856 IAC 3-2-1
856 IAC 3-2-3
856 IAC 3-2-7
856 IAC 3-2-8
856 IAC 3-3
856 IAC 3-4
856 IAC 3-5
856 IAC 3-6
856 IAC 3-7

SECTION 1. 856 IAC 3-1-2 IS ADDED TO READ AS FOLLOWS:

856 IAC 3-1-2 "Chain drug warehouse" defined
Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 2. As used in IC 25-26-14 and in this article, "chain drug warehouse" means a permanent physical location for drugs or devices, or both, that:
(1) is licensed as a wholesale distributor;
(2) acts as a central warehouse; and
(3) primarily performs intracompany sales and transfers of legend drugs or devices to chain pharmacies that are members of the same affiliated group under common ownership and control.
(Indiana Board of Pharmacy; 856 IAC 3-1-2)

SECTION 2. 856 IAC 3-1-3 IS ADDED TO READ AS FOLLOWS:

856 IAC 3-1-3 "Statement" defined
Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 3. "Statement" means the specific unit of the specific legend drug that was purchased directly from the manufacturer.
(Indiana Board of Pharmacy; 856 IAC 3-1-3)

SECTION 3. 856 IAC 3-2-3 IS AMENDED TO READ AS FOLLOWS:

856 IAC 3-2-3 Application forms; renewal forms
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 3. (a) Applications for licensure may be obtained by writing to the Indiana Board of Pharmacy, ~~Health Professions Bureau,~~

Indiana Professional Licensing Agency, 402 West Washington Street, Room ~~041,~~ **W072,** Indianapolis, Indiana 46204.

(b) Wholesale drug distributor licenses shall expire on September ~~30th~~ **30** of each even-numbered year. Applications for renewal shall be mailed to the licensee. *(Indiana Board of Pharmacy; 856 IAC 3-2-3; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; errata filed Aug 24, 1992, 9:00 a.m.: 16 IR 66; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)*

SECTION 4. 856 IAC 3-3 IS ADDED TO READ AS FOLLOWS:

Rule 3. Accreditation

856 IAC 3-3-1 Board-approved accreditation body
Authority: IC 25-26-14-13; IC 25-26-14-14
Affected: IC 25-26-14-14

Sec. 1. The National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors (VAWD) program shall do the following:
(1) Evaluate a wholesale drug distributor's operations to determine compliance with the following:
(A) Industry standards.
(B) IC 25-26-14.
(C) This title.
(D) Any other applicable law.
(2) Perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesale drug distributor.
(3) Ensure that the information obtained during accreditation remains confidential and privileged.
(4) Adhere to other requirements set by the board or the Indiana professional licensing agency.
(Indiana Board of Pharmacy; 856 IAC 3-3-1)

856 IAC 3-3-2 Accreditation for new applicants
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 2. For licenses issued after December 31, 2005, applicants for licensure as wholesale drug distributors shall obtain the accreditation from the National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors (VAWD) program before issuance of licensure. *(Indiana Board of Pharmacy; 856 IAC 3-3-2)*

856 IAC 3-3-3 Accreditation for existing license holders
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 3. For licenses issued before January 1, 2006, license holders shall obtain the accreditation from the National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors (VAWD) program before renewal of licensure on September 30, 2006. *(Indiana Board of Pharmacy; 856 IAC 3-3-3)*

SECTION 5. 856 IAC 3-4 IS ADDED TO READ AS FOLLOWS:

Rule 4. Pedigrees

856 IAC 3-4-1 Pedigrees; contents
Authority: IC 25-26-14-8.7; IC 25-26-14-13
Affected: IC 25-26-14

Sec. 1. A pedigree for each legend drug shall contain the following information:
(1) The legend drug proprietary and established name.
(2) The container size of the legend drug.
(3) The number of containers.

(4) The dosage form.
(5) The dosage strength.
(6) Lot/control numbers with expiration dates.
(7) The name of the manufacturer and repackager, if applicable, of the finished legend drug product.
(8) The name, address, and telephone number of each entity involved in the chain of the legend drug's custody.
(9) The name and address of each person certifying delivery or receipt of the legend drug.
(10) The sales invoice number.
(11) The dates of each transaction, including manufacturer, delivery, and receipt.
(12) A certification that each recipient has authenticated the pedigree, back to the manufacturer.
(13) A certification from the licensed entity that the information contained on the pedigree is true.
(Indiana Board of Pharmacy; 856 IAC 3-4-1)

856 IAC 3-4-2 Pedigrees; approved formats
Authority: IC 25-26-14-8.7; IC 25-26-14-13
Affected: IC 25-26-14

Sec. 2. The pedigree format:
(1) shall include the contents described in section 1 of this rule; and
(2) may be subject to the approval of the board.
(Indiana Board of Pharmacy; 856 IAC 3-4-2)

SECTION 6. 856 IAC 3-5 IS ADDED TO READ AS FOLLOWS:

Rule 5. Normal Distribution Chain of Custody

856 IAC 3-5-1 Authorized distributor to authorized distributor transaction; pedigree requirement
Authority: IC 25-26-14-8.5; IC 25-26-14-13
Affected: IC 25-26-14-17

Sec. 1. For purposes of IC 25-26-14 and this article, within the normal distribution chain of custody, an authorized distributor that receives a legend drug directly from the manufacturer, or from the manufacturer's third party logistics provider, may sell the legend drug to a pharmacy, chain drug warehouse, or practitioner or one (1) other authorized distributor of the manufacturer that sells the legend drug directly to a pharmacy, chain drug warehouse, or practitioner without passing a pedigree if the invoice or accompanying document for the transaction includes a statement that the product was purchased directly from:
(1) the manufacturer; or
(2) an authorized distributor of the manufacturer who purchased the product directly from the manufacturer.
(Indiana Board of Pharmacy; 856 IAC 3-5-1)

856 IAC 3-5-2 Chain drug warehouses in the normal distribution chain of custody
Authority: IC 25-26-14-8.5; IC 25-26-14-13
Affected: IC 25-26-14-1.8; IC 25-26-14-17

Sec. 2. As used in IC 25-26-14 and in this article, chain drug warehouses that are distributing to their affiliated pharmacies or warehouses are not required to:
(1) be recognized as an authorized distributor, as defined in IC 25-26-14-1.8, for the normal distribution chain of custody to apply; or
(2) within the normal distribution chain of custody, pass a pedigree to or between their affiliated pharmacies or warehouses.
(Indiana Board of Pharmacy; 856 IAC 3-5-2)

856 IAC 3-5-3 Entities within the normal distribution chain custody
Authority: IC 25-26-14-8.5; IC 25-26-14-13
Affected: IC 25-26-14-17

Sec. 3. All entities, other than manufacturers approved by the Food and Drug Administration, within the normal distribution chain of custody shall be located and licensed within the United States or its territories. *(Indiana Board of Pharmacy; 856 IAC 3-5-3)*

856 IAC 3-5-4 Applicability of normal distribution chain of custody
Authority: IC 25-26-14-8.5; IC 25-26-14-13
Affected: IC 25-26-14-17

Sec. 4. Normal distribution chain of custody applies to the following:
(1) Physical movement of the legend drug.
(2) Its passage of title.
(Indiana Board of Pharmacy; 856 IAC 3-5-4)

SECTION 7. 856 IAC 3-6 IS ADDED TO READ AS FOLLOWS:

Rule 6. Drug Returns

856 IAC 3-6-1 Drug returns; pedigree requirement
Authority: IC 25-26-14-11; IC 25-26-14-13
Affected: IC 25-26-14-17

Sec. 1. The returns or exchanges of saleable legend drugs, received by the wholesale distributor as provided by this article, are not subject to the pedigree requirements under IC 25-26-14 and 856 IAC 3-4. Wholesale distributors are responsible for the following:
(1) Policing the returns process.
(2) Maintaining operations that are designed against the entry of an adulterated or counterfeit product into distribution.
(Indiana Board of Pharmacy; 856 IAC 3-6-1)

SECTION 8. 856 IAC 3-7 IS ADDED TO READ AS FOLLOWS:

Rule 7. Authentications

856 IAC 3-7-1 Authentication
Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 1. Manufacturers shall cooperate in the process of authentication, as defined in IC 25-26-14. *(Indiana Board of Pharmacy; 856 IAC 3-7-1)*

SECTION 9. THE FOLLOWING ARE REPEALED: 856 IAC 3-2-1; 856 IAC 3-2-7; 856 IAC 3-2-8.

SECTION 10. **SECTIONS 1 through 9 of this document take effect January 1, 2006.**

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on September 12, 2005 at 10:00 a.m., at the Indiana Professional Licensing Agency, Indiana Government Center-South, 402 West Washington Street, Conference Room W064, Indianapolis, Indiana the Indiana Board of Pharmacy will hold a public hearing on proposed amendments to implement rule changes based on House Enrolled Act 1098-2005, including establishing criteria for drug returns, establishing the definitions and requirements for normal distribution chain of custody, pedigree, and the extent to which pedigrees are required, and establishing criteria to approve an accreditation body to evaluate and inspect a person who engages in wholesale distributions of legend drugs.

The Indiana Board of Pharmacy has the authority to promulgate rules in accordance with the requirements of HEA 1098 (P.L.212-2005). The requirements of HEA 1098 and this proposed rule help ensure that counterfeit drug product does not enter Indiana's drug distribution system and ultimately protects the patients of Indiana from such drug product. The recognition of the National Association of Boards of Pharmacy's (NABP) Verified-Accredited Wholesale Distributors (VAWD) Program allows the

Board to enforce such stringent licensing requirements and standards. The VAWD program is another example of the quality regulatory assistance that NABP has provided the Board for the past 100 years. If not for the VAWD program, the Indiana Professional Licensing Agency and the Board would incur a significant fiscal and operational impact, as they would be required to inspect and ensure compliance of licensed wholesalers across the United States. In sum, recognition of the NABP's accreditation program mitigates the fiscal and operational impact on the state and on the Board by authorizing VAWD to conduct inspections and ensure compliance with state and federal law. This proposed rule will have cost on the regulated entities, as follows:

The cost for each accreditation will be as follows:

Initial accreditation fee: $5,500 (includes inspection costs)

Annual participation fee:

$1,000, if not an inspection year

$ 4,000, if an inspection year (inspections occur every 3 years)

There are approximately 490 to 540 wholesale drug distributor licensees that will be required to obtain initial accreditation from NABP's VAWD program, which in total will cost the regulated entities between $2,695,000 and $2,970,000 within the first 12 months the rule is in effect. Following the initial accreditation, the total cost to the regulated entities will be between $490,000 and $540,000 based on the annual participation fee not in an inspection year. The total cost to the regulated entities will be between $1,960,000 and $2,160,000 based on the annual participation fee in an inspection year.

Copies of these rules are now on file at the Indiana Government Center-South, 402 West Washington Street, Room W072 and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Frances L. Kelly
Executive Director
Indiana Professional Licensing Agency